

Essence of the Joint Controllers' Arrangement (“JCA”) for the VOLABIOS Project — Public Summary

The partners of the scientific research project - “Validation and Comparative Multi-Omics Benchmarking of Fluid-Derived Volatilomics Biomarkers for the Prevention and Early Detection of Schizophrenia” (Hereinafter referred to as “**Volabios Project**” and/or “**Project**”) act as joint controllers for pseudonymized personal data processed during the research activities conducted under Grant Agreement No. 101156162.

In line with Article 26 of the General Data Protection Regulation (“**GDPR**”), the partners of Volabios Project consortium are in the process of establishing a Joint Controller Arrangement setting out how they share responsibilities for ensuring compliance with data protection obligations.

Based on transparency requirements set out under Articles 13 and 14 of the GDPR, the essence of the Joint Controller Arrangement is provided in the table below.

**DATA PROCESSING SUMMARY – JOINT CONTROLLER ARRANGEMENT**

<p><b>Identity of the joint controllers and their contact details</b></p>	<ul style="list-style-type: none"> <li>• TECH - ISRAEL INSTITUTE OF TECHNOLOGY SENATE BUILDING TECHNION CITY, HAIFA 32000, Israel. <a href="mailto:hossam@technion.ac.il">hossam@technion.ac.il</a>;</li> <li>• EXUS - SOFTWARE MONOPROSOPI ETAIRIA PERIORISMENIS EVTHINIS. THEANOUS 15, ATHENS 118 54, Greece. <a href="mailto:m.panniello@exus.ai">mailto:m.panniello@exus.ai</a>;</li> <li>• SAS - SERVICIO ANDALUZ DE SALUD. AVENIDA DE LA CONSTITUCION 18, SEVILLA 41071, Spain. <a href="mailto:alberto.moreno.sspa@juntadeandalucia.es">mailto:alberto.moreno.sspa@juntadeandalucia.es</a>;</li> <li>• FISEVI - FUNDACION PARA LA GESTION DE LA INVESTIGACION EN SALUD DE SEVILLA. <a href="mailto:fjose.nunez@juntadeandalucia.es">mailto:fjose.nunez@juntadeandalucia.es</a>;</li> <li>• UKA - UNIVERSITAETSKLINIKUM AACHEN. Pauwelsstrasse 30, AACHEN 52074, Germany. <a href="mailto:tfrodl@ukaachen.de">tfrodl@ukaachen.de</a>;</li> <li>• FIRALIS - RUE DU FORT 35, HUNINGUE 68330, France. <a href="mailto:hueseyin.firat@firalis.com">hueseyin.firat@firalis.com</a>;</li> <li>• TLX – TIMELEX, JOSEPH STEVENSSTRAAT 7, BRUSSEL 1000, Belgium. <a href="mailto:Vaisakh.shaji@timelex.eu">Vaisakh.shaji@timelex.eu</a>;</li> <li>• AINIGMA – AINIGMA TECHNOLOGIES. KAPELDREEF 60, LEUVEN 3001, Belgium. <a href="mailto:d.ntenekou@ainigma.tech">d.ntenekou@ainigma.tech</a>;</li> <li>• CERTH - ETHNIKO KENTRO EREVNAS KAI TECHNOLOGIKIS ANAPTYXIS. <a href="mailto:stefanos@iti.gr">stefanos@iti.gr</a>;</li> </ul>
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<p><b>Purpose(s) of processing and legal basis</b></p>	<p><b>Purpose of processing:</b> Research activities conducted under Grant Agreement No. 101156162 - Validation and Comparative Multi-Omics Benchmarking of Fluid-Derived Volatilomics Biomarkers for the Prevention and Early Detection of Schizophrenia.</p> <p>Each Clinical partner remains responsible for the personal data it collects and contributes to the Project; whereas collective decisions guide how the data are used, analyzed, retained and shared within the Project.</p> <p>Processing is carried out solely for scientific research purposes within the scope of the Project, in accordance with GDPR and relevant ethical standards.</p>

	<p>The pseudonymized data collected from data subjects may be further processed for future research purposes determined as per the Project's sustainability plan at the end of the Project and/or for future studies on identification of diagnostic or therapeutic signatures or on biological underpinnings of schizophrenia. Biological samples collected from data subjects as part of the Project's clinical study may also be stored in a bio-bank developed at the end of the Project for creation of a pan-EU biobank node for schizophrenia.</p> <p><b>Legal basis:</b> The legal basis for collecting, storing and processing of pseudonymized personal data in line with agreed protocols for scientific research conducted under the scope of the Project based on GDPR and respective national laws of the consortium partners are:</p> <ul style="list-style-type: none"> <li>• Processing of pseudonymized personal data for scientific research purposes for retrospective study contributed by Clinical partners based on Article 6(1)(e) and Article 9(2)(i) or 9(2)(j) GDPR;</li> <li>• Prospective clinical studies conducted on patients by Clinical partners based on patient explicit consent under Article 6(1)(a) and Article 9(2)(a) GDPR.</li> </ul>
<p><b>Categories of personal data/ special categories of personal data collected/ processed/ stored</b></p>	<p>Shared pseudonymized datasets containing health data, such as data from electronic health records, data derived from human bodily samples for multi-omics analysis, clinical assessment data collected from patient interview and questionnaire, psychiatric history data, geo-spatial health data, volatile organic compound data derived from human bodily samples.</p> <p>Personal identifiers of the pseudonymized data remains strictly under the control of the Clinical partners. The Technical partners which will receive the pseudonymized data from the Clinical partners to carry out their research tasks will not be able to re-identify the data subjects. Support partners will not access the pseudonymized data.</p>
<p><b>Adherence to data protection principles</b></p>	<p>All processing operations respect fundamental data protection principles of lawfulness, fairness, transparency, data minimization, integrity and confidentiality.</p>
<p><b>Recipients or categories of recipients of personal data</b></p>	<p>The datasets collected and contributed by the Clinical partners will be shared with the Project's Technical partners for processing as per the Project's agreed protocols.</p>
<p><b>Third country transfer</b></p>	<p>Transfer to and from UK based on Commission Implementing Decision of 28 June 2021 and Commission Decision and Israel based on Commission Decision of 31 January 2011 and Commission Implementation Decision of 16 December 2016.</p>

<b>Retention period (or criteria for erasure)</b>	Personal data collected as part of clinical study will be retained for a minimum period of ten years for complying with applicable regulatory requirements for retention and audit. Pseudonymized personal data will be retained after the end of the project and will be re-used for future analysis or scientific research purposes based on informed explicit consent obtained from data subjects taking part in the clinical study.
<b>Data subject rights</b>	<p>The JCA transparency provisions respects the following data subject rights mentioned in the GDPR:</p> <ul style="list-style-type: none"> <li>• Right to withdraw consent – free to withdraw consent at any time;</li> <li>• Right of access and data portability – right to receive information on whether or not personal data are processed and right to request transfer to a portable electronic data storage medium;</li> <li>• Right of rectification or erasure of personal data – personal data corrected in case of inaccuracies;</li> <li>• Right of deletion – right to have personal data deleted if these data are no longer needed;</li> <li>• Right to restriction of processing – to limit how personal data is processed.</li> </ul>
<b>Statutory or contractual necessity/ consequences of not providing personal data</b>	<p>Personal data processed under the Volabios Project is for scientific research purposes based on legal bases mentioned above (public interest, scientific research, informed explicit consent). Personal data collected for clinical studies are based on voluntary consent of the data subjects participating in the study. The data subjects can exercise their right to withdraw consent at any time.</p> <p>If the data subject withdraws consent, all personal data stored up to that point will not be further processed as part of the Project’s clinical study and will only be retained for the purpose of regulatory compliance pertaining to retention and audit. The withdrawal of consent does not affect the lawfulness of processing based on consent before its withdrawal.</p>
<b>Automated decision-making/ profiling</b>	No profiling or exclusive automated decision making activity is undertaken as part of processing for scientific research.
<b>Responsibility of each of the Joint Controllers</b>	<ul style="list-style-type: none"> <li>• Project planning, management and coordination – TECH;</li> <li>• Legal support – TLX;</li> <li>• Ethics support – UKA, SAS, LSMU, ZSI;</li> <li>• Data and sample storage and processing infrastructure – EXUS (lead) along with SAS, FISEVI, FIRALIS, CERTH, AINIMGA, CUBIC;</li> <li>• Retrospective data collection and analysis – AINIGMA (lead) along with SAS, FISEVI, UKA, UDUS;</li> </ul>

	<ul style="list-style-type: none"> <li>• Volatilomics and multi-omics tool development – SNSI (lead) along with TECH, UKA, FIRALIS;</li> <li>• Clinical studies design and preparatory activities – UKA (lead) along with TECH, EXUS, LSMU, FIRALIS, UC, CERTH, SAS, UCAM;</li> <li>• Impact creation – EXUS;</li> <li>• Implementation of clinical studies – UKA (lead) along with SAS, FISEVI, LSMU, FIRALIS, EXUS, MOHGR, UC,UCAM;</li> <li>• Clinical study data collection, processing and analysis – UKA (lead) along with TECH, SNSI, FIRALIS, UC, UCAM, SAS,FISEVI, LSMU, FIRALIS, EXUS, CERTH CUBIC.</li> </ul>
<b>Contact point</b>	<p>For any questions or requests relating to the processing of personal data within the Project, the patients should contact the principal investigator/ clinician who conducted their clinical assessment at their clinical centre. Patients may also contact the project coordinator via <a href="mailto:info@volabios.eu">info@volabios.eu</a>.</p>
<b>Accessibility and updates</b>	<p>This summary will be maintained and updated on <a href="http://www.volabios.eu">www.volabios.eu</a> for the duration of the Project.</p>